

U. S. FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Talking With Stakeholders About FDA Modernization

The Executive Board of the Association of Food and Drug Officials (hereafter referred to as AFDO) is pleased to provide comments to the Food and Drug Administration (FDA) as input for specific agency performance targets. AFDO is proud of its tradition for working very closely with FDA and other federal agencies whose missions parallel ours for developing strategies to resolve and promote public health and consumer protection issues related to the regulation of foods, drugs, medical devices, and consumer products. AFDO applauds the openness of FDA and its willingness to seek stakeholder input.

FDA requests that stakeholders address five questions for which we provide the following comments:

1. *What actions do you propose the agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision making?*

Response

AFDO strongly supports decision-making based on sound science and improved risk-assessment tools. The FDA can expand its capability by support and utilization of available university and regulatory networks through cooperative activities, not the least of which is the Joint Institute for Food Safety and Nutrition (JIFSAN). Through appropriate utilization of JIFSAN, FDA should delineate and prioritize public health issues requiring science basis, particularly those where current science is weak, emerging, or non-existent. JIFSAN should incorporate stakeholders in setting priorities. AFDO believes that JIFSAN offers a unique academic partnership that can enrich FDA's decision making science needs. JIFSAN should also be used to evaluate other science that impacts on the agency's mission and in doing so should utilize an advisory group which offers a cross section of FDA's networks with state and local governments, consumer groups and other academic entities. Most decision-making is set in a scientific, social, political, and regulatory framework which makes it more important for all of these to be brought to the decision making table to ensure the necessary buy-in and support. FDA cannot operate in a vacuum in any of these areas.

AFDO strongly believes there is the need for FDA to counsel with other regulatory officials from federal, state, and local governments regarding their experiences in addressing various food safety issues. State officials should continue to be utilized by FDA, using the credentialing process, to provide valuable input into proposed regulations and regulatory enforcement schemes the agency may utilize to obtain compliance.

Additionally, AFDO believes that academia must be continually utilized on advisory committees and work groups which are designed for dealing with particular public health concerns.

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2. *What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's life cycle?*

Response

AFDO has previously testified at public meetings that FDA must be the scientific leader and singular body for dispersing scientific information to government at all levels. AFDO's vision of a national integrated food safety system recognizes the critical nature of this matter as we continue to promote this concept. Although state and local government should continue to provide input on products throughout its development and marketing life cycle, FDA needs to be the centralized body for publicizing the final decision on scientific matters.

FDA cannot assume this leadership role without the buy-in of its stakeholders. Therefore, it necessitates that FDA develop a forum, perhaps an advisory committee, to openly discuss the issues which arise. The agency is tending to do this through the use of public meetings, but frequently the notice is short and many who should be involved cannot. FDA needs to look for a better way, or a more long-range approach to anticipate issues where public health and science must converge to bring resolution in a decision-making situation.

To implement an effective integrated approach to exchange of scientific information of regulatory significance, CFSAN desperately needs to develop a streamlined internal tracking system that will ensure state officials receive timely responses to inquiries. FDA technical staff should be empowered to provide answers without having to forward draft responses through multiple layers of bureaucracy. State officials should be willing to accept a verbal reply, if possible, although FDA must be sensitive to the needs of state officials who may need responses in writing to convince regulated industry or consumers of the regulatory position on an issue. State officials can no longer wait months to receive replies on scientific or technical matters. This is particularly important when dealing with regulatory issues where it involves an interpretation of a federal law or regulation.

3. *What actions do you propose for educating the public about this concept of balancing risks against benefits in public health decision making?*

Response

Articles on risk, written in layman's terms and giving examples from everyday life, should be used in any FDA documents that are produced for the general public. Only by giving such examples can the general public understand risk as it refers to the safety of foods and drugs. FDA public affairs specialists should be encouraged to address health risks and the importance of consumer education with all interested persons and groups with whom they meet. Furthermore, AFDO supports the formation of state task forces comprised of all public health stakeholders for the purpose of debate and education.

4. *Because the agency must allocate its limited resources to achieve the greatest impact, what actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?*

Response

Where there are issues that involve a "perception" that FDA disagrees philosophically with an industry or a category of regulated products, FDA must meet both privately and publicly with these stakeholders to ensure "on the record" that the perception is incorrect. For example, if the public or some segments of industry continue to distrust FDA with respect to the regulation of dietary supplements, little headway can be made with respect to ensuring the safety and proper labeling of the products in the marketplace, or the development of future products.

AFDO also encourages FDA to better establish and maintain its communication network with state and local government agencies. Too often, FDA regional and district guidance or response to state and local government members differ from FDA centers. This results in a confused message and negative credibility. AFDO suggests the further development of field coordinator positions in sensitive high risk areas such as product recalls and epidemiological investigations so those individuals can serve as singular contacts during these serious events.

5. *Because the agency wants to assure that its stakeholders are aware of and participate in its modernization activities, what additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?*

Response

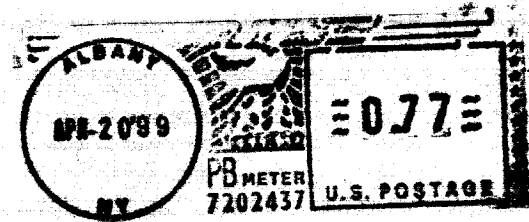
AFDO supports the continuation and/or development of work groups to provide necessary feedback and evaluation of serious health matters. AFDO hopes FDA can continue to fund the activities of such groups as the National Integrated Food Safety System Work Groups, FDA/AFDO Recall Work Group, Foodborne Outbreak Response Coordination Group (FORCE-G), FoodNet/Emerging Infections Program, and others established to coordinate and better utilize government resources at all levels.

AFDO appreciates the opportunity to comment on these very important matters.

Submitted by: Joseph Corby, President
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